

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 99D-0463]

Foods—Adulteration Involving Hard or Sharp Foreign Objects; Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled “Foods—Adulteration Involving Hard or Sharp Foreign Objects.” This CPG is intended to help FDA components and industry comply with FDA’s internal enforcement process concerning foods that contain hard or sharp foreign objects.

DATES: Written comments on this CPG may be submitted at any time.

ADDRESSES: Submit written requests for single copies of Compliance Policy Guide (CPG) Sec. 555.425 “Foods—Adulteration Involving Hard or Sharp Foreign Objects” to the Director, Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-827-0482. Copies of the CPG may also be downloaded to a personal computer with access to the World Wide Web (WWW). The Office of Regulatory Affairs (ORA) home page includes the CPG and may be accessed at “<http://www.fda.gov/ora>”. The CPG will be available on the Compliance References page for ORA.

Submit comments to MaryLynn A. Datoc, the second contact person listed in this document in the “**FOR FURTHER INFORMATION CONTACT**” section.

FOR FURTHER INFORMATION CONTACT:

Technical Questions Concerning Foreign Objects in Foods: Alan R. Olsen, Microanalytical

Branch (HFS-315), Office of Plant, Dairy Foods, and Beverages, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4438, FAX 202-205-4091.

Questions Concerning Regulatory Actions and All Comments: MaryLynn A. Datoc, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0413, FAX 301-827-0482.

SUPPLEMENTARY INFORMATION: FDA has developed a CPG to provide guidance on FDA's internal enforcement process concerning foods that contain hard or sharp foreign objects. This guidance synthesizes FDA's case-by-case responses to the problem of hard or sharp foreign objects in food. The CPG is intended to provide clear policy and regulatory guidelines to FDA's field and headquarters staff with regard to such foods. It also contains information that may be useful to the regulated industry and to the public.

Therefore, FDA has prepared a CPG to describe its internal enforcement process. The CPG is being issued as a guidance document and represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This CPG is being issued as a level 2 guidance consistent with GGP's.

Interested persons may submit to the second contact person listed in this document written comments regarding the CPG entitled "Foods—Adulteration Involving Hard or Sharp Foreign Objects." Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading

of this document. A copy of the CPG and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 23, 1999

A handwritten signature in cursive script, reading "Gary Dykstra", is written over a horizontal line.

Gary Dykstra
Acting Associate Commissioner for Regulatory Affairs

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